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Article (Accepted Version)

Roscoe, Samuel and Blome, Constantin (2019) Understanding the emergence of redistributed manufacturing: an ambidexterity perspective. *Production Planning and Control*, 30 (7). pp. 496-509. ISSN 0953-7287

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**Understanding the emergence of redistributed manufacturing:
an ambidexterity perspective**

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Abstract

The purpose of this paper is to extend operations management theory concerning efficiency and flexibility trade-offs to the emergent phenomenon of redistributed manufacturing (RDM). The study adopts a multiple case design including five small and five large pharmaceutical firms. By synthesising the research findings and extant literature we propose organisations can gain the efficiency benefits of centralised manufacturing and the flexibility advantages of RDM by building an ambidexterity capability. To build such a capability, large firms can structurally partition their manufacturing and supply management functions, with one sub-unit managing centralised production and the other RDM. Small and medium enterprises can build an ambidexterity capability by creating the right organisational context, one in which a multi-skilled workforce switches between efficient and flexible tasks. This paper contributes to theory by explaining the emergence of RDM using an organisational ambidexterity lens, laying the groundwork for new theory development in the field. The paper contributes to managerial thinking by providing practical examples of how managers can build an ambidexterity capability to realise flexibility and efficiency advantages.

Keywords: Redistributed manufacturing, organisational ambidexterity, supply networks, 3D printing, additive manufacturing

This work was supported by the Engineering and Physical Sciences Research Council (EPSRC) under grant number EP/M017559/1 - Redistributed Manufacturing in Healthcare Network (RiHN)

1. Introduction

Manufacturing systems are in a constant state of evolution. In the 1980s the world witnessed a shift from mass production lines to 'lean' production systems (Milgrom and Roberts 1990; Womack, Jones, and Roos 1990). In the late 1990s agile supply chains emerged allowing fast fashion companies to quickly respond to fluctuations in customer demand (Christopher 2000; Lee 2004). Then, in the early 2000s, mass customisation systems promised companies the ability to efficiently manufacture products for individual consumers on a large scale (Pine 1999). Each of these fundamental shifts in manufacturing systems has been enabled by significant advances in technology (e.g. Barcodes, Radio Frequency Identification).

Today, a new evolution in manufacturing is taking place. Redistributed Manufacturing (RDM) promises organisations the ability to flexibly respond to demand by using distributed facilities to manufacture close to the customer. RDM is defined as the transformation from a 'current state' to a 'future state' using new production and infrastructural technologies, and involves a radical change in the geographical dispersion of production facilities, normally from a high volume centralised model to a lower volume dispersed factory model, located closer to the point of use (Srai, Harrington, and Tiwari 2016, p. 1). A manufacturing system is the arrangement and operation of machines, tools, material, people, and information to produce a value-added physical informational, or service product whose success and cost is characterized by measurable parameters (Cochran and Dobbs 2001 p. 372).

As with other transformative manufacturing systems that came before, RDM is enabled by major technological advancements, particularly in the case of additive manufacturing, or, 3D printing. 3D printing creates three-dimensional artefacts through layer-by-layer deposition of materials (Ford and Minshall 2015). One advantage of 3D printing is that it allows companies to distribute manufacturing to a variety of sites near to the point of consumption whilst still maintaining uniform outputs (Ford and Minshall 2015). One drawback, however, is that RDM fails to capitalise on the efficiency gains that are associated with the mass production of goods within a centralised facility.

The trade-offs that exist between efficient and flexible manufacturing systems is a phenomenon long examined by operations management (OM) scholars (see De Meyer et al. 1987; Kannan 1998; Grant 1991; Hill 1993; Hayes and Wheelwright 1984; Skinner 1969, 1985). One group of scholars suggest that companies should pursue either a low cost competitive strategy supported by efficient operational processes, or a strategy of differentiation supported by more flexible processes (Hill 1993; Markides 2006; Porter 1980, 1996). According to these scholars, attempting to reconcile two opposing systems is likely to result in organisations becoming stuck in the middle, leading to high switching costs (Porter 1980, 1996; Markides 2006). However, another group of scholars suggests that organisations can manage the trade-offs associated with efficient and flexible production systems by developing an ambidexterity capability (Adler, Goldoftas, and Levine 1999; Duncan 1976; Gibson and Birkinshaw 2004; Tushman and O'Reilly 1996). These scholars believe that ambidextrous organisations tend to be successful precisely because they are both efficient in the management of daily business demands and adaptive enough to flexibly respond to changes in the business environment (Gibson and Birkinshaw 2004; Tushman and O'Reilly 1996).

More recently, the notion of ambidexterity has been extended beyond the boundaries of the firm to the supply chain. For example, Kristal, Huang and Roth (2010) find that supply chain managers can build practices to gain operational efficiency while simultaneously searching for opportunities to gain operational advantages associated with

flexible processes. Similarly, Blome Schoenherr, and Kaesser (2013) find that organizational ambidexterity can enhance the innovation outputs of buyer-supplier engagements while Rojo, Llorens-Montes and Perez-Arostegui (2016) find that building a supply chain ambidexterity capability can help firms to achieve an optimal level of supply chain flexibility.

These studies demonstrate that OM theory is reaching consensus that efficiency and flexibility is not an either-or decision. Instead, OM scholars now acknowledge the complementarities between efficient and flexible manufacturing systems and find they can co-exist within a focal firm's supply chain. The purpose of our study is to further extend OM theory surrounding efficiency and flexibility trade-offs to the emergent phenomenon of redistributed manufacturing. Our aim is to answer the question: how can firms reconcile the efficiency advantages of a centralised manufacturing system with the flexibility advantages of a redistributed manufacturing system?

To answer this question we study the pharmaceutical industry; a sector that in the past predominately used a centralised manufacturing model to minimise production costs, but is now exploring the use of smaller and more agile facilities to support dispersed manufacturing models (Srai et al. 2015). We use the manufacturing and supply management functions of the focal firm as the units of analysis to understand how new and existing manufacturing systems can be integrated. We take an abductive approach continuously moving between theory and data to arrive at a robust set of findings (Josephson and Josephson 1996; Suddaby 2006). Specifically, we use organisational ambidexterity as a theoretical lens to examine empirical data gathered from ten case companies in the pharmaceutical industry.

The remainder of the paper is divided into four sections. The next section reviews the discourse surrounding efficiency/flexibility trade-offs and ambidexterity. We then provide justifications for the research design, data collection and analysis methods. The findings from a multiple-case study of UK pharmaceutical firms are then presented. The paper concludes by synthesising the research findings and extant literature to set out a framework for future RDM research – laying the groundwork for new theory development in the field of RDM.

2. Literature Review

2.1 The Flexibility and Efficiency Trade-offs of Manufacturing Systems

Skinner (1969, 1974, 1985), one of the first authors in the OM field to explore efficiency-flexibility trade-offs, argued that while the role of the manufacturing function is to support a company's strategy, it cannot effectively do so when trying to meet multiple performance objectives. Similarly, Hayes and Wheelwright (1984) stressed that the manufacturing function should concentrate on one performance objective, be it efficiency or flexibility, to achieve optimum results. Building on this notion, Hill (1993) argued that companies should set out clear competitive objectives, such as whether to compete based on cost or responsiveness, and then develop manufacturing processes to support the delivery of these objectives. These authors propose an either-or perspective, suggesting that an organisation should select one primary performance objective and then design suitable manufacturing systems to enable delivery.

Such views are supported by leading management scholars such as Porter (1996), who argues that companies that try to compete simultaneously on low cost and

differentiation strategies risk degrading the value of existing activities whilst paying huge straddling costs. Other scholars such as Kurke (1988) argue that efficiency requires a bureaucratic form of organisation with high levels of standardisation, formalisation, specialisation and hierarchy; it is exactly these bureaucratic features that impede the fluid process of mutual adjustment required for flexibility (ibid). Markides (2006) supports this argument when he states that integrating an innovative new business model within an existing business unit can often be difficult because of various trade-offs or conflicts between the two ways of doing business (Markides 2006).

This school of thought has been challenged by another group of scholars who find too simplistic the notion that firms must follow an either-or strategy (Adler, Goldoftas, and Levine 1999; De Meyer et al. 1987). Due to today's hypercompetitive environment these authors argue it is no longer sufficient for firms to pursue only one objective or strategy (Melnyk et al. 2010). In their view, firms should instead pursue multiple strategies but to differing degrees to ensure competitive survival (Schoenherr and Mabert 2011; Reimann and Sarkis 1996).

2.2 Ambidexterity in Supply Chains

An organization's ability to pursue two disparate activities at the same time is termed organisational ambidexterity (Adler, Goldoftas, and Levine 1999). Duncan (1976) was the first to discuss the notion of structural ambidexterity, suggesting that organisations manage the trade-offs between conflicting demands by putting in place dual structures where certain sub-units focus on alignment while others focus on adaptation. In their study of the Toyota Production System, Adler, Goldoftas and Levine (1999) found that production can be both efficient and flexible if the organisation partitions itself to allow some sub-units to specialise in routine tasks while other sub-units specialise in non-routine tasks. Doing so allows the firm to exploit the cost advantages associated with repetitive routines whilst simultaneously exploring for new flexible manufacturing systems during non-routine work (Adler, Goldoftas, and Levine 1999). Similarly, Tushman and O'Reilly (1996) discovered that a firm can achieve superior performance by competing in mature markets in which cost efficiency and incremental innovation are critical, whilst developing new products for emerging markets in which experimentation, speed and flexibility are essential.

More recently, Kortmann et al. (2014) explained that two ambidextrous operational capabilities (mass customization and innovative ambidexterity) can fully mediate the relationship between strategic flexibility and operational efficiency. They argue that firms that emphasize organizational diversification create flexible strategies by investing in ambidextrous operational capabilities that yield both radical and incremental production innovations (Kortmann et al. 2014). Patel et al. (2012) also examined the role of ambidexterity capabilities and found that firms with greater operational ambidexterity capabilities are more likely to respond to demand as well as technical and competitive uncertainty by pursuing manufacturing flexibility. Organizational Ambidexterity has also been found by Tomayo-Torres (2017) to act as enabler across quality, speed, flexibility and cost dimensions, therefore driving manufacturing performance

Gibson and Birkinshaw (2004) placed more importance on creating the right organizational context when nurturing an ambidexterity capability. They suggest senior management teams can establish an organisational context that empowers employees to make their own choices as to how they divide their time between alignment (efficient) and adaptability-oriented (flexible) activities. Such a context is created by informally encouraging employees to strive for ambitious objectives (stretch), to meet all expectations generated by their explicit or implicit commitments (discipline), to lend assistance and

countenance to others (support) and to rely on the commitments of each other (trust) (Gibson and Birkinshaw 2004).

Common across much of the ambidexterity literature is an examination of the trade-offs between efficiency and flexibility within the boundaries of the firm. Only recently has a handful of authors sought to understand how organisations achieve ambidexterity outside of a firm's boundaries; in the supply chain (e.g. Blome, Schoenherr, and Kaesser 2013; Kristal, Huang, and Roth 2010). Kristal, Huang and Roth (2010) define supply chain ambidexterity as a manufacturing firm's strategic choice to simultaneously pursue both supply chain exploitation (efficiency) and exploration (flexibility) practices (Kristal, Huang, and Roth 2010 p. 415). Im and Rai (2008) found that knowledge sharing leads to relationship performance gains and that such sharing is enabled by the ambidextrous management of buyer-supplier relationships. Blome, Schoenherr and Kaesser (2013) found that buyers can gain synergistic benefits by pursuing both contractual supplier relationships, often associated with cost efficiencies, and relational engagements, which provide flexibility benefits. Rojo, Llorens-Montes and Perez-Arostegui (2016) move beyond the buyer-supplier dyad to identify that building a supply chain ambidexterity capability can help firms to achieve an optimal level of supply chain flexibility. Likewise, Lee and Rha (2016) find that supply chain ambidexterity is important as firms mitigate the negative impact of supply chain disruptions, thereby enhancing business performance.

By studying the efficiency/flexibility debate over the decades it becomes evident that OM theory is converging on the opinion that a firm's supply chain can be both efficient and flexible – or ambidextrous. However, we are no closer to understanding how a focal firm can realize the efficiency benefits of a centralised manufacturing system and the flexibility benefits of RDM. The purpose of this paper is to extend OM theory concerning efficiency and flexibility trade-offs to the emergent phenomenon of RDM. The steps we took to examine the RDM phenomenon are now explained in greater detail.

3. Research Design

The researchers took an abductive approach to answer the research question, moving back and forth between theory and data (Suddaby 2006). Specifically, we used organisational ambidexterity as a theoretical lens and gathered data on a current trend in the pharmaceutical industry: firms maintaining centralised manufacturing whilst building smaller and more agile facilities to support dispersed manufacturing models (Srai et al. 2015).

We followed the advice of Yin (2014) and used a case study research design because the research question has a 'how' framing and examines a recent phenomenon about which relatively little is known. A case study design is ideally suited to our investigation because it lends itself to early, exploratory investigations in which the variables are still unknown and the phenomenon (i.e. RDM) is not at all understood (Voss, Tsikriktsis, and Frohlich 2002). We selected a multiple, over a single, case study design as it offers more opportunities for in-depth data gathering and analysis (Dyer and Wilkins, 1991). Moreover, a multiple case design allows for both within- and across-case comparisons, and is often considered more robust than single-case designs (Yin, 2014).

Many of the leading studies on organisational ambidexterity have used case studies of large multi-national enterprise (MNE) firms (see Tushman and O'Reilly 1996). The particular focus on large MNEs is interesting because small and medium enterprises (SMEs) compete in the same hypercompetitive markets as multi-nationals and require the same ability to switch between efficient and flexible processes. Therefore, we extended our

sampling frame to include MNE and SME pharmaceutical firms, with one company representing one case.

Our sampling logic was to conduct preliminary interviews with key experts at a UK pharmaceutical policy body. Drawing on their in-depth knowledge about the UK pharmaceutical industry, these experts helped identify case companies that could assist in answering the research question. Based on their advice, and to allow comparisons according to firm size, we studied five MNEs and five SMEs. The policy experts introduced us to key contacts at the case companies and we then used a snowball sampling logic to identify potential interviewees. Snowball sampling is a non-probability sampling technique in which existing subjects recruit future subjects from among acquaintances in their social network until the desired sample size is reached (Morgan 2008). A potential drawback of convenience sampling is that the sample may not be representative of the population. However because of confidentiality concerns, the researchers found the only way to gain access to prospective interviewees was through fellow employees at each case company.

We accounted for construct validity, internal validity, external validity, and reliability throughout the research process (Gibbert, Ruigrok, and Wicki 2007; Yin 2014). To enhance construct validity, the researchers interviewed key informants and used a triangulated data collection approach including semi-structured interviews, focus groups and secondary data. Triangulation improves the validity of research findings, as it allows the researcher to see that multiple sources of data have led to the same results (Bogdan and Biklen 2007). Triangulation also limits confirmation bias, which is the tendency of people to favour information that confirms their beliefs or hypotheses (Plous 1993).

Key informants were interviewed including senior supply chain executives, supply chain consultants and managing directors, each of whom could give informed comment on their company's manufacturing systems and supply chains (see Table 1). Expert opinion was also gathered from leading academics in the fields of innovation, additive manufacturing, life sciences and pharmaceuticals. Twenty-five semi-structured interviews were conducted, each lasting between forty-five minutes and one hour. Interviews were tape-recorded and transcribed verbatim. Transcriptions were sent to interviewees for review and amendment. A total of twenty-two hours of interview recordings and 375 pages of transcripts were collected.

-Insert Table 1 Here-

The interview findings were corroborated through a series of eight focus groups. Thirty experts in RDM from industry and academia were invited to a one-day knowledge exchange event at the University of Sussex in March, 2016. During the event, participants were split into focus groups where they were challenged to identify the enablers and barriers of adopting RDM systems in pharmaceutical supply chains.

The cumulative findings were then objectively verified using primary and secondary data sources. Primary documentation gathered from the case companies included new technology business cases and procurement and supply chain strategy documentation. Secondary data sources included websites, policy documents and annual reports. Data collection stopped when a point of theoretical saturation had been reached or, more specifically, when additional data did not provide new information or understanding (Eisenhardt 1989).

To enhance internal validity, the researchers followed the advice of Braun and Clarke (2006) and used a process of pattern matching and explanation building, considering rival

explanations throughout the data analysis process. Using thematic analysis techniques, the researchers adopted a pattern matching logic to group similar codes together and to identify first-order descriptions, or themes. The initial coding structure used to analyse the data is shown in Table 2 and includes the first order descriptions of structural ambidexterity and contextual ambidexterity. When analysing the data, the researchers also considered potential complementarities between an efficient and flexible manufacturing system.

-Insert Table 2 Here-

Through an iterative process of analysing transcripts and revising the coding template, the researcher arrived at a final template that provided a robust explanation of the cases. NVivo 10 software was used to code the interview transcripts, focus group notes and company documentation.

The researchers also took steps to enhance external validity. Rather than attempting to generalise the findings to a wider population, as with statistical generalisation, the researchers generalised the findings to a broader theory, a process called analytical generalisation (Yin 2014). Specifically, the researchers set out to augment organisational ambidexterity theory by examining the RDM phenomenon and the inherent trade-offs companies face when adopting such a system.

To enhance reliability, the researchers established a chain of evidence throughout the data collection and analysis process by creating a case study protocol and case study database (Ellram 1996). Providing a chain of evidence enhances reliability by allowing future researchers to follow the steps taken by the researcher and to arrive at the same or similar conclusions (Ellram 1996; Yin 2014). Table 3 provides a summary of the steps taken to enhance the validity and reliability of the findings.

-Insert Table 3 Here-

4. Research Findings

During data analysis, a distinct difference in opinion emerged between managers working at large MNEs and those working at SMEs. The following section teases out these differences by first considering the findings that relate to structural ambidexterity with responses split by MNE and SME managers. The findings are further informed by expert academic opinion.

4.1 Exploiting the Efficiency Advantages of Centralised Production

During the interviews, it emerged that all MNE managers (MNE 1-5) had a strong preference for maintaining the centralised manufacturing model due to the low per unit cost of production and the high sunk costs of facilities and equipment. MNE managers repeatedly mentioned that their companies had invested heavily in an efficient, centralised manufacturing system designed to produce small molecule tablets and generic pills at the lowest possible cost. These views are expressed in Table 4 as follows:

-Insert Table 4 Here-

The consensus of MNE managers was that the current means of centralised production are so cost effective that their companies would remain focused on exploiting these cost advantages (see Table 3). A review of business case documentation from MNE 1-5 revealed that when these companies are considering a new technology, the innovation must demonstrate cost savings over current technologies to be adopted. As MNE's are intensely cost focused, it becomes difficult to make a convincing business case for the adoption of a more flexible and responsive manufacturing system such as RDM, thereby confirming our interview and focus group findings.

At the same time, interviews with supply chain and additive manufacturing academics suggest MNE manager's particular focus on the per-unit production cost of centralised manufacturing may, in fact, be misguided. When discussing the trade-offs between centralisation and re-distribution, one academic expert stressed that instead of focusing on per-unit production costs, firms should instead consider total system costs:

'That per-unit production cost is not what you should be looking at, it is the total system cost that is important...half the inventory in the warehouse is going to go to landfill because it's not being used. The inefficiency in the supply chain is a cost that is often forgotten.'

- *Supply Chain Management Academic Expert*

The preceding quote stresses that while the centralised model can produce a generic pill at a very low cost, the system is underpinned by significant amounts of inventory. Typically, inventory in a pharmaceutical supply chain equates to thirty to ninety percent of annual demand, with anywhere between four and twenty-four weeks' worth of finished good stocks being held at any one time (Shah 2004). Indeed, the top twenty-five pharmaceutical companies are said to hold inventory in the range of \$100-150 billion at any one time (Harrington and Srai 2014). Not only do MNEs have high inventory carrying costs, they also face high instances of inventory write-downs due to expired or unwanted stock (Harrington and Srai 2014; Shah 2004). Interestingly, a review of business cases at MNE 1-5 showed that these companies considered the fixed costs of plant and equipment and variable costs such as labour and raw materials when considering new technologies. However, we did not find a consideration of the inventory carrying costs associated with current production technologies and whether new technologies or manufacturing systems could reduce inventory holdings. When one considers the total system cost of centralised production, including inventory carrying costs across the supply chain, it becomes easier to make a convincing business case for the adoption of redistributed manufacturing systems.

4.2 Theme 2: Exploring the Flexibility Advantages of RDM

SME managers (SME1-5) were found to be more open to the idea of utilising an RDM system than were their MNE counterparts. The findings suggest this was primarily because SMEs managers prioritised flexibility and responsiveness over cost. One interviewee at SME1 discussed the importance of locating production close to the point of need as it allows a quick and flexible response to customer demand (see Table 5).

Academic experts also highlighted the many benefits of using 3D printers in distributed production facilities. Some of the advantages include quicker changeover times, lower retooling costs and the ability to personalise medicines for patients. 3D printing permits a wide range of product specifications to be created on one machine; this capability,

coupled with reduced need for retooling or line changeovers, enhances speed and embeds flexibility into the production process.

-Insert Table 5 Here-

The quotes in Table 5 suggest that using 3D printing within an RDM system allows for the personalisation of medicines, an emergent and highly lucrative market in the pharmaceutical industry. As highlighted by Srai et al. (2015) in their paper about the future of the pharmaceutical industry, advances in personalised medicines will require product customisation that makes the batch-centric production models of today incapable of economically supplying product varieties at the smaller volumes required, and at the speed increasingly demanded by end-users, without costly inventory holdings. As the RDM system locates production close to the customer, redundant nodes in the supply chain are removed, thereby reducing the need for buffer stock. Moreover, the production of personalised medicines within an RDM system creates the potential for increased profit margins, offsetting the higher set-up and running costs of the RDM model.

Up until this point, centralised manufacturing and RDM have been cast as two opposing systems. Yet, as the researchers continued collecting and analysing data, new findings emerged that indicated the two systems should not be seen as substitutes, but instead as complements to one another.

4.3 Theme 3: Complementarities between Centralised Manufacturing and RDM

Despite its many advantages, the majority of academic and managerial interviewees felt that RDM is not likely to entirely replace centralised manufacturing. Instead, most interviewees believed the two systems should be seen as complementary, a sentiment captured in the following quote:

Many evangelists in this industry say ‘3D printing is a substitute technology to others’. However, the more conservative approach is to say ‘okay, 3D printing technology will be some sort of complement to actual manufacturing lines’.

-Academic Expert 1- Additive Manufacturing

The preceding quote suggests 3D printing is likely to be only one technology in the spectrum of manufacturing technologies already in use by most MNE firms. As RDM is not likely to totally replace centralised production, it becomes imperative to understand how RDM can complement the centralised system.

During the focus group sessions, the researchers encouraged participants to explore potential complementarities between RDM and centralised production. As with the interviewees, the general consensus of focus group participants was that an RDM system does not make economic sense for the mass production of small molecule and generic drugs due to the sunk costs and low production prices of the centralised system. Focus group members felt that RDM is more applicable to the production of personalized medicines including advanced therapy medicinal products (ATMPs), large molecule and biological drugs. This group of medicines is more costly to manufacture and tends to have higher profit margins, thus more readily justifying the high overhead costs of distributed facilities and initially expensive 3D printing technology. Moreover, these types of products tend to be highly personalised and targeted at small patient populations, a market ideally suited to

the RDM model. The potential complementarities between centralised manufacturing and RDM as seen by MNE and SME managers are shown in Table 6.

-Insert Table 6 Here-

The quotes in Table 6 suggest that RDM is best suited to the production of high value, personalised medicines targeted at small patient populations such as advanced therapeutics (ATMPs) and gene therapies. Other potential applications of an RDM system include the manufacture and distribution of compound products, such as infusion bags that are uniquely tailored to the patient. Pharmaceutical firms are hesitant to develop compound products through conventional means due to the prohibitively high costs associated with carrying out stability studies and gaining regulatory approval each time the product/package mix is altered.

Late-stage dispensing also emerged as a suitable RDM application. In the UK, the Royal Pharmaceutical Society has recently permitted decentralised dispensing, opening up the possibility of hospital pharmacies using 3D printing to produce drug combinations. Such a distributed dispensing system would be in marked contrast to the current process in which complete pill packs are received from the manufacturer, and hospital staff then de-blister the packs into small personalised packages, generating excessive waste throughout the process (see Table 6).

The production of radioactive pharmaceuticals was seen as another potentially viable option which, in effect, currently uses a RDM model. In the radio pharmacy model, a hospital pharmacist prepares the radioactive injectable on-site, allowing it to be administered to a patient in a matter of hours before it dissipates. Additive manufacturing could complement such a model with the product created on-site and administered immediately, based on patient need (see Table 6).

Finally, the Operations Director at MNE5 stressed that using 3D printers within an RDM system would allow for the creation of poly-pills, which contain multiple active ingredients within one pill. While some focus group participants felt that the validation and regulation of combining multiple actives into one pill would prove challenging, others saw poly-pills as the future of the pharmaceutical industry (see Table 6).

Despite the researcher's attempts to identify passages of text relating to the contextual ambidexterity themes of alignment and adaptability, none could be found in the data. The researchers specifically looked for passages of text mentioning terms such as discipline, support, trust, employee empowerment, judgement and multi-skilled employees; however these concepts were not mentioned by the interviewees or focus group participants. Furthermore, a review of secondary documentation at MNEs and SMEs, including Human Resource Management policy documents and annual reports, did not reveal data relating to the five aspects of contextual ambidexterity. This is most likely because the majority of the companies studied are yet to adopt an RDM system and have therefore not established the internal structures and management mechanism necessary for a contextually based ambidexterity capability. As many firms are still in a pre-adoption phase, we now synthesize the research findings and extant literature to propose ways in which MNE and SME firms can adopt an RDM system.

5 Framework for Future RDM Research

The following section draws on the literature and case study findings to set out a research agenda for the emergent topic of RDM. The research agenda is based on three propositions that can be tested by researchers during future studies of RDM. Our research findings indicate that RDM is still in a pre-adoption phase, with most managers still considering whether to embrace a distributed mode of manufacturing. The data revealed a preference of MNE managers to maintain the centralised manufacturing model due to cost advantages, whilst SME managers more readily recognized the flexibility advantages of the RDM model. Importantly, both MNE and SME managers were able to recognize the complementarities that exist between the two models. Table 7 presents a cross-case comparison of the codes that fall under the three themes of efficiency, flexibility and complementarities.

-Insert Table 7 Here-

The codes contained in Table 7 indicate that organizational size influences how managers are likely to foster an ambidexterity capability. MNEs have an employee base numbering in the tens of thousands with intricate organizational hierarchies, leading to significant levels of complexity (Adler 2011). Due to such complexity, creating an organisational context that allows a multi-skilled workforce to quickly switch between alignment (efficient) and adaptability (flexible) tasks may prove prohibitively difficult. To overcome such complexity, we suggest that MNE managers are more likely to build an ambidexterity capability using structural partitioning.

The general consensus of MNE managers was that the high over-head costs of distributed facilities are only justifiable for low volume, high margin and customizable products such as gene and cell therapies, ATMPs, large molecule drugs and biologics. MNE managers are therefore likely to maintain the production of small molecule and generic drugs within centralised facilities and, as new trends such as personalised medicines emerge, consider more flexible manufacturing systems such as RDM. The structural partitioning in MNE's is therefore expected to occur according to product type.

The Adler, Goldoftas and Levine (1999) study of the adoption of lean management systems identified that novel forms of organizational partitioning enable differentiated subunits to work in parallel on routine (efficient) and non-routine (flexible) task. Toyota's subsidiary reallocated responsibilities across partitions, in particular through job enrichment for workers and more active involvement of suppliers (Adler, Goldoftas, and Levine 1999). Like with lean, we suggest that RDM adoption by MNEs will be enabled by structurally partitioning the manufacturing function into two sub-units. One sub-unit of the manufacturing function would oversee the efficient production of standardised products such as generics and small molecule drugs within a centralised manufacturing systems. The other sub-unit would be responsible for the flexible production of personalised medicines within a re-distributed system (see Figure 1).

-Insert Figure 1 Here-

Duncan (1976) expresses a note of caution however, stating that partitioning can lead to parochial, self-interested subunit behaviour, multiplying the management overhead required to reconcile intra-organizational conflict. To counteract such parochial practices, we stress that, once partitioned, the two sub-units must share knowledge and best practice. By doing so, we propose the focal firm will benefit from enhanced flexibility and efficiency. The following proposition is thus advanced:

Proposition 1: Structurally partitioning the manufacturing function into centralised manufacturing and RDM sub-units will lead to enhanced flexibility and efficiency for MNEs.

We observe that MNE firms need to extend partitioning to the supply chain because the majority of primary and secondary materials used in pharmaceutical products come from suppliers. Complexity plagues MNE supply chains due to a high numbers of suppliers, often numbering in the thousands, as well as multiple supplier tiers (Prater, Biehl, and Smith 2001). Roerich and Lewis (2014) find that as systemic complexity increases in the supply chain so does the focal firm's reliance on contractual governance mechanisms. They argue that the use of simplified contractual governance in the form of working agreements combined with relational governance, such as inter-personal relationships, can be effective in counteracting complexity. Similarly, Kreye, Roehrich and Lewis (2015) find that as service complexity increases so does the level of relational capability development. Well-developed relational capabilities, in turn, prevent conflicts and promote the exchange of information (Kreye, Roehrich, and Lewis 2015). Cao and Lumineau (2015) also find complementarities between formal contracts and relational governance mechanisms and argue that contracts, trust, and relational norms jointly improve satisfaction and relationship performance.

We suggest that to overcome complex supply chain structures, MNE firms should begin by partitioning the area of the business responsible for supplier management, such as the procurement or supply chain management unit. One subunit of the supply management function would be responsible for the centralised manufacturing system while the other oversees the RDM system (see Figure 2).

-Insert Figure 2 Here-

Figure 2 shows that the RDM sub-unit is responsible for controlling the flow of active ingredients and powders to local production facilities and, if required, any onward distribution to the patient. The local manufacturing site may be a hospital, as in the case of compound infusion bags, or a pharmacy, as in the instance of personalised drug combinations (poly-pills) for patients. The focal firm may also choose to have local production sites around the country to distribute personalised medicines (i.e., gene therapies) directly to patients. After diagnosing the patient, the personalised medicine would be produced on-site using 3D printing technology (see Figure 2). The centralised manufacturing sub-unit would focus on driving cost efficiencies with suppliers using contracting mechanisms. The RDM subunit would use relational mechanisms such as trust and collaboration to enhance flexibility in the supply network. We therefore propose the following:

Proposition 2a: Structurally partitioning the supply management function into centralised manufacturing and RDM sub-units will lead to enhanced flexibility and efficiency for MNEs.

Proposition 2b: Effective partitioning of the supply management function will be enabled by using contracting mechanisms to oversee the centralised manufacturing system and relational governance mechanisms to manage the RDM system

While large resource pools allow MNEs to operate two manufacturing systems in parallel, we propose that SMEs should take a different approach. One advantage of having fewer employees is that SMEs are better able to create a multi-skilled workforce able to switch between alignment (efficiency) and adaptability (flexibility) tasks. Instead of partitioning based on product type, we propose that SME production and supply managers can oversee the production of high volume, low margin products in a centralised facility whilst simultaneously managing the production of highly customizable products in distributed facilities (see Figure 3).

-Insert Figure 3 Here-

According to Gibson and Birkenshaw (2004) creating the right organizational context for ambidexterity requires managers to follow four steps; 1) to create informal routines that prompt employees to stretch for ambitious objectives; 2) to meet all expectations in a disciplined manner; 3) to support team members in their daily roles and; 4) to create an environment of trust between team members. Figure 3 shows that the centralised and RDM facilities would be kept physically separate, meaning the production and supply manager would need to facilitate fluid communication, trust and teamwork between the operational employees at the respective manufacturing sites. In the RDM system, manufacturing would occur across a range of distributed facilities including hospitals, pharmacies or facilities owned by the focal firm. The centralised production system would run in parallel to the RDM system and also be managed by the production and supply managers. We therefore propose the following:

Proposition 3a: By creating an organizational context based on the goals of trust, support, stretch and discipline, SME production and supply managers can switch between the management of a centralised and redistributed manufacturing system.

Proposition 3b: By building a contextually based ambidexterity capability SMEs can gain the efficiency advantages of a centralised manufacturing system and the flexibility benefits of a redistributed manufacturing system.

6 Contribution, Limitations and Future Research Directions

We now conclude with a discussion of the paper's theoretical and managerial contributions and potential methods for testing the propositions in future RDM studies.

6.1 Theoretical Contribution

The purpose of this paper is to extend OM theory concerning flexibility and efficiency trade-offs to the emergent area of RDM. The paper makes a theoretical contribution by creating a future research agenda for RDM consisting of three propositions. Our examination of the pharmaceutical industry suggests MNEs will continue with efficient, centralised manufacturing systems and then as new markets emerge, including personalised medicines, begin to adopt more flexible manufacturing systems such as RDM. We posit that MNEs can build an ambidexterity capability by structurally partitioning their manufacturing unit and mirroring this segmentation in the supply management function. Suppliers to the centralised systems will be governed by formal contracting mechanisms to realize cost efficiencies, while suppliers to the RDM system will be governed by relational mechanisms such as collaboration and trust to gain flexibility advantages.

Although SMEs have smaller resource pools than their MNE counterparts, lower levels of complexity can act in their favour. Fewer employees and a flatter organisational hierarchy are likely to make it easier to create a multi-skilled workforce able to switch between routine and non-routine tasks. SME managers can thus build an ambidextrous organisational context by implementing formalised training procedures to develop a multi-skilled manufacturing and supply management function and by using informal mechanisms to instil discipline, support and trust amongst teams (Gibson and Birkinshaw 2004). Ambidextrous production and supply managers can efficiently manage suppliers to the centralised manufacturing systems using formalized contracting mechanism and encourage flexibility by using relational governance mechanisms with suppliers to the RDM system.

6.2 Managerial Contribution

This paper challenges managers to not see efficiency and flexibility as an either-or trade-off, but instead as complementary. The paper provides MNEs managers with practical examples of how their manufacturing and supply management functions can be partitioned to pursue both efficiency and flexibility objectives. SME managers are encouraged to create a multi-skilled manufacturing and supply management team able to switch between alignment (efficient) and adaptability (flexible) processes.

The structurally partitioned model suggested for MNEs is inherently different than the paradigms of 'leagility' and mass customisation. These two concepts advocate switching between routine and non-routine production processes within the same facility. Instead, we suggest that the centralised manufacturing system and the RDM system are kept separate using discrete facilities. The centralised manufacturing sub-unit exploits the economies of scale associated with manufacturing within centrally located facilities whilst the RDM sub-unit explores the flexibility advantages of being close to the patient and delivering personalised medication via distributed facilities.

6.3 Research Limitations

The authors acknowledge that limitations exist with the current paper. We do not claim that our findings are generalisable to wider populations or other industries (i.e. statistical

generalisation). Instead, we aim for analytical generalisation by abstracting the findings to a broader theory; organizational ambidexterity (Yin 2014). Future researchers could generalise the findings to a wider population by testing the propositions using quantitative techniques such as surveys or questionnaires. The current study is also limited by its use of qualitative data, which is susceptible to researcher bias (Eisennhardt 1989). Following the advice of Yin (2014), the researchers took steps to reduce bias and improve the validity and reliability of the findings. Specifically, we followed a detailed case study protocol, designed a case study database and checked case findings with key informants. Despite these measures, the researchers acknowledge that bias may still be present in the interpretation of findings.

6.4 Future Research Directions

As RDM is still in the pre-adoption phase, there is much work to be done on this important topic. To assist in this endeavour, our paper sets out a future research agenda for RDM. Our findings suggest a primary reason for the slow uptake of RDM is that many people view it as a disruptive manufacturing system. Instead, we suggest that RDM should be seen as complementary to existing centralised production systems; best suited to low volume, high margin and personalized products. Our framework for future RDM research sets out three propositions where centralised manufacturing and RDM act as complements. In the near term, we challenge future researchers to test our propositions using case studies either in the pharmaceutical sector, or other industries. In the medium to long term, once RDM systems are more widely adopted, we challenge researchers to test the propositions using quantitative methods such as surveys or questionnaires.

Future researchers could also extend our study beyond the focal firm to examine how MNE firms structurally partition their supply chains using contracting and relational mechanisms. Such a study would require researchers to collect data from multiple supply chain tiers. Researchers could also use a network perspective to investigate how contracting and relational governance mechanism can enable an ambidextrous supply network.

Acknowledgements

The authors would like to acknowledge the support of the Engineering and Physical Sciences Research Council (EPSRC) in carrying out this research. We are also grateful to the Redistributed Manufacturing in Healthcare Network (RiHN) for guidance and support throughout the research project.

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Table 1: Case company background

Case	Area of Expertise	# of employees	# of interviews	Company turnover	Interviewee Position(s)
MNE1	R&D and manufacture of medicines and consumer healthcare products	+10,000	2	£25-50bn	-Supply chain transformation lead, -Global procurement transformation lead
MNE2	Biopharmaceutical R&D and manufacture of medicines, consumer healthcare products and vaccines	+10,000	3	£1-5bn	-Production Director, -Director Global Warehousing, -Global Operations Procurement Director
MNE3	Develops, manufactures and sells pharmaceutical and biotechnology products	+10,000	2	£25-50bn	-Senior Director -Vice President of Supply Operations
MNE4	R&D and manufacture of prescription drugs	+10,000	3	£1-5bn	-Commercial Director, - Commercial Manager, - Director Group Procurement
MNE5	Develops, manufactures and sells biopharma products	+10,000	1	£25-50bn	-UK Operations Director
SME1	Immunotherapy R&D and manufacture	100-1000	1	£25-50mil	Operations Director
SME2	Pharmaceutical Consultancy	100-1000	1	Not available	Process Engineer
SME3	Pharmaceutical Consultancy	<100	1	Not available	CEO
SME4	Distance Selling pharmacy	<100	1	Not available	Director of Business and Product Development
SME5	Advisers to pharmaceutical policy groups and UK government	<100	1	Not available	Managing Director
Academic Experts	Expertise: additive manufacturing, supply chain management, innovation, life sciences	Not applicable	7	Not applicable	Senior Lecturer(s)/Professor(s)
Policy Experts	Experts in informing UK pharmaceutical policy	Not applicable	2	Not applicable	Director, Project Manager

Table 2: Initial Coding Template

Theory	First Order Descriptions	Themes	Coding Identifiers
Organizational Ambidexterity	Structural Ambidexterity	Exploitation	• Efficiency – cost focus
		Exploration	• Flexibility– responsiveness focus
		Complementarities between efficiency and flexibility	• Potential synergies between efficient and flexible manufacturing systems
	Contextual Ambidexterity	Alignment and Adaptability	<ul style="list-style-type: none"> • Interaction of stretch, discipline, support, and trust • Set of processes or systems that enable individuals to make their own judgments about how to divide their time between conflicting demands for alignment and adaptability

Table 3: Measures taken to enhance validity and reliability

Quality of Research Design	Case Selection and design	Data Collection	Data Analysis
Construct validity	Not applicable	-Triangulated data collection strategy-interviews, focus groups, primary and secondary documentation (Yin, 2014) -Use of highly knowledgeable informants considered experts in their particular area (Eisenhardt, 1989)	-Data analysis in parallel to interview phase to be receptive to new results (Eisenhardt, 1989.) -Establish and maintain a chain of evidence – case study protocol and database (Ellram, 1996; Yin, 2014) -Draft reports viewed by key informants (Ellram, 1996)
Internal validity	-Cross case comparisons (Yin, 2014)	-Use of highly knowledgeable informants considered experts in their particular area (Eisenhardt, 1989) -Multiple respondents (Ellram, 1997)	-Pattern matching among cases (Yin, 2014) -Active search for alternative explanations (Braun and Clarke, 2006; Yin, 2014)
External validity	-Comparative multiple case study approach (Ellram, 1996, Yin, 2014)	-Gathering data on the case context (Gibbert et al. 2008)	-Consideration of case context (Johns 2006) -Extensive intra-case analysis (Eisenhardt, 1989) -Analytical generalization (Yin, 2014)
Reliability	-Established a chain of evidence including case study protocol and database (Ellram, 1996, Yin, 2014)	-Semi-structured interview guide included in case study protocol (Yin, 2014)	-All interview transcripts analysed by interviewers (Yin, 2014)

Table 4: Theme 1: Exploiting the cost efficiencies of centralized manufacturing

Code	MNE Manager
Current business model based on large volumes and low variety-too expensive to move to RDM model	‘Why would you try to adapt a mass-volume, low variety business model to provide customised medication? We're so far away from that ... it takes so much investment’ -- <i>Supply chain transformation lead MNE1</i>
Centralized manufacturing offers economies of scale	‘You're almost better, if you can, to produce a larger volume, with a fixed head count because the moment you branch out to doing the same thing and replicating it in another market, it increases your costs.’ – <i>Global operations director- MNE 2</i>
Centralized manufacturing has very high sunk costs-making it difficult to justify move to RDM	‘Where it [RDM] doesn’t add value is where you have good distribution networks and you have a product that can get through those distribution networks in a timeframe that meets the patient need but also meets any product restrictions and requirements.’ – <i>Senior Director- MNE3</i>
Duplication of facilities and management structures in RDM model brings higher costs	‘The cost is probably going to go up, so what's the benefit of having a local plant that can do it? Because you've got regulatory issues, you've got quality issues, What are the practicalities of running a duplicate outfit somewhere else, when you could just make your current facility bigger?’ - <i>Commercial Manager-MNE4</i>
Per unit production costs very low in centralized model	There’s a lot of sunk capital in the current technologies, and most of that investment has been fully depreciated over the years. The cost of making the tablet by conventional means is something like 1 US cent or 1 Euro cent. So if 3D printing a tablet costs any more than that, there's the question of well, why do it that way if you can do it the conventional way?- <i>UK Operations Director-MNE5</i>

Table 5: Theme 2: Exploring the flexibility advantages of RDM

Code	SME
RDM brings production closer to the point of need	‘The alternative is, instead of scale up, we look at scale out. So start off small and if sales increase you can ramp up your production from scaling out, through smaller, more localised facilities, closer to the point of need. So rather than having a big centralised facility that’s a long way away from potential markets you can locate them closer to where they’re needed’ - <i>Operations Director – SME1</i>
RDM model applicable for cell and gene therapies	‘Potentially you can use distributed manufacturing with these small items such as the cell handling mechanisms that you need for the cell therapies or the gene therapy that you are going to be deploying’ - <i>Process engineer- SME2</i>
Personalization of medicines can offset costs of RDM system	‘You might incur a higher average cost, but because you’re offering a customised or personalised product, a medicine that might have additional benefits through customisation that then may more than offset the cost disadvantage.’ - <i>CEO – SME3</i>
Currently using distributed model to send pharmaceutical products to patients	‘A lot of pharmaceutical products are made centrally... produced en-masse for large populations, and then sent out all over the world. But what we're looking at is this idea of local manufacturing for local delivery, where the idea is to have the technology to package medication in local areas, and then dispatch directly out to the customer’ - <i>Director of Business and Product Development- SME4</i>
Customizability of RDM offsets costs advantage of centralized production	‘The key to understanding the attractiveness of 3D printing for the pharmaceutical industry ...even if the average cost will be higher than for a conventional route, is that because we can personalise medicine, effectively we can derive greater benefits that then might outweigh the added cost as well’.- <i>Managing Direct-SME 5</i>

Table 6: Theme 3: Complementarities between centralized production and RDM

Code	MNE	SME
RDM is suited to the production of biopharma products	‘It will potentially work in biopharma because the economies of scale in biopharma manufacturing seem to be coming down. So you make biopharma in reactors which have capacity. It seems that whereas a 20,000 litre capacity which used to be the efficient manufacturing scale seems to coming down to 2,000, or 3,000 litres. Whereas tableting lines don't seem to be getting much smaller in economies of scale.- <i>Global procurement transformation lead – MNE1</i>	
Mnfg. plants can be distributed inside of hospitals	‘There is one model that's been around for decades called radio pharmacy, for radioactive medicines. You have a mini-manufacturing plant, if you like, and, within the space of 15 minutes, you make the radioactive pharmaceutical injectable, out of this additive manufacturing machine...It's preparing a specific pharmaceutical product for a specific patient, at a specific dose, at the time of use.’ - <i>Global Operations Procurement Director MNE2</i>	‘But in cell therapy you've got things like the CAR-T therapy that's come down the line, and smart, small, integrated manufacturing models to treat people for autologous therapies for cancer treatments. You don't build big factories for that; you have a distributed manufacturing capability. You'll stick some of these small units on the side of a hospital to deliver that patient performance’ – <i>Process Engineer-SME2</i>
RDM is suited to ATMPs and Biologics but not small molecule drugs	For ATMPs and biologics it (RDM) might make sense. But for small molecules? I would suggest, forget it. You're not going to get drug manufacturing to be distributed for small molecule products.- <i>Senior Director- MNE3</i>	You need to find things where RDM is absolutely pivotal to the viability of the approach you're talking, and it could be creating some sort of part-plastic, part-cell construction that's specific to the patient in the operating theatre, you do it real time, it's entirely custom, but it involves manufacturing processes that are quite complicated, and you're not making thousands a minute, you're making one. <i>CEO-SME 3</i>
RDM ideal for formulating patient specific treatments on-site at the hospital	‘Compounding is an example where, we had some discussion within NHS England when they said ‘Actually what we'd really like you to do is just deliver infusion bags ready for patient use. We don't really want our pharmacies to have to do that anymore’. That would be near-to-hospital, near-to-point-of-use, which would be very much personalised to that individual. That's an unmet need, definitely.’ – <i>Commercial Manager MNE 4</i>	It works well with these tailored cancer treatments. Quite often what they can do is take the bulks to the hospital and then they formulate the specific treatment they need for that patient there in the hospital, which works quite well- <i>Operations Director-SME 1</i>
RDM suited to combining active ingredients in one pill	‘It [3D printing] potentially allows you to put more than one drug in to a tablet, which is very difficult at the moment. Poly pills are probably going to be the way drugs are delivered in the future because modern medicine is going to be relying on multiple actives rather than single active. Like how you might think in terms of, HIV medication is multiple actives.’ – <i>UK Operations Director MNE 5</i>	

Table 7- Cross-case comparison of data coding

Case company	Coding Summary		
	<i>Exploitation (Efficiency)</i>	<i>Exploration(flexibility)</i>	<i>Complementarities</i>
MNE 1	Current business model based on large volumes and low variety-too expensive to move to RDM model		RDM is suited to the production of biopharma products
MNE 2	Centralized manufacturing offers economies of scale		Manufacturing plants can be distributed inside of hospitals
MNE 3	Centralized manufacturing has very high sunk costs-making it difficult to justify move to RDM		RDM is suited to ATMPs and Biologics but not small molecule generic drugs
MNE 4	Duplication of facilities and management structures in RDM model brings higher costs		RDM ideal for formulating patient specific treatments on-site at the hospital
MNE 5	Per unit production costs low in centralized model		RDM suited to combining active ingredients in one pill (poly-pills)
SME 1		RDM brings production closer to the point of need	RDM ideal for formulating patient specific treatments on-site at the hospital
SME 2		RDM model applicable for cell and gene therapies	Manufacturing plants can be distributed inside of hospitals
SME 3		Personalization of medicines can offset costs of RDM system	RDM is suited to ATMPs and Biologics but not small molecule drugs
SME 4		Currently using distributed model to send pharmaceutical products to patients	
SME 5		Customizability of RDM offsets costs advantage of centralized production	

Figure 1: Structurally Partitioned Manufacturing Function in MNEs

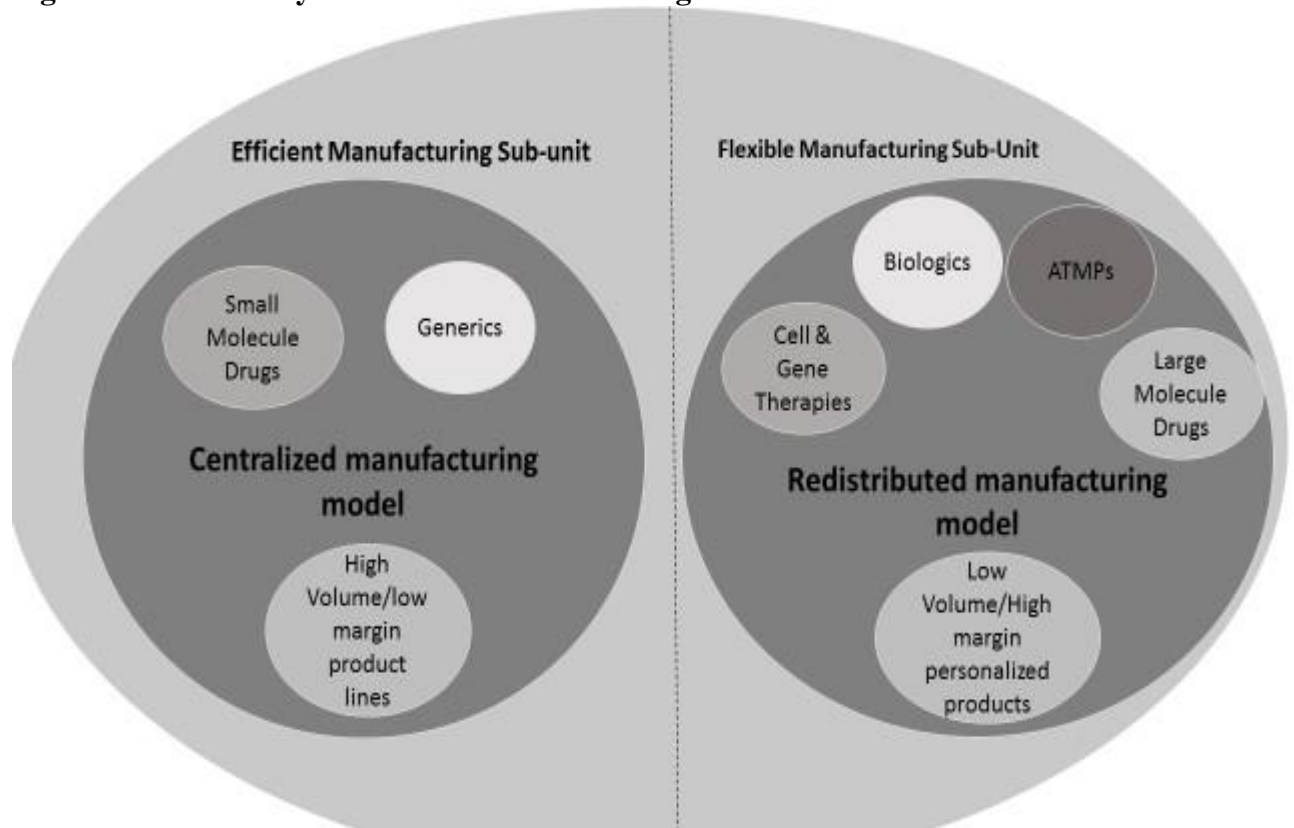


Figure 2: Structurally Partitioned MNE Supply Chain

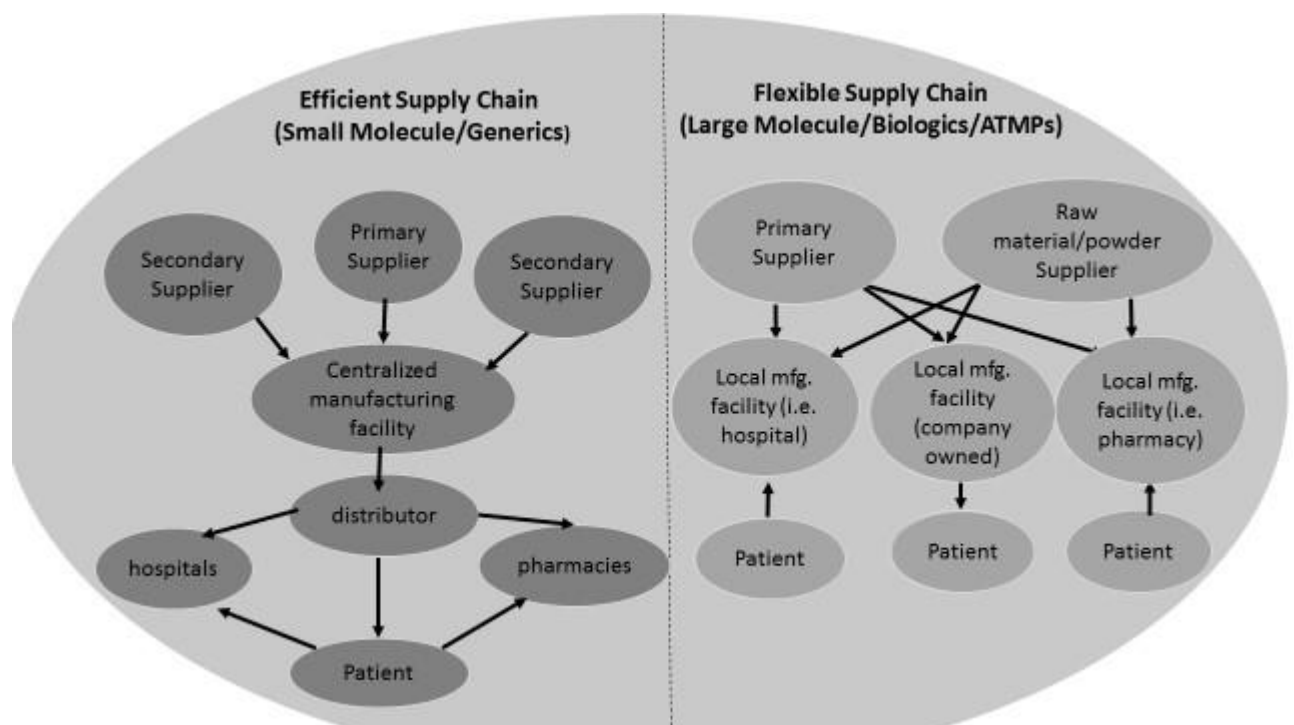


Figure 3: Contextual ambidexterity of SME's

